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IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

BOLAR PHARMACEUTICAL CO., INC.,
Petitioner,

v.

ROCHE PRODUCTS, INC.,
Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF AMICUS CURIAE OF THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI IN SUPPORT OF AFFIRMANCE

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INTEREST OF AMICUS CURIAE

This brief *amicus curiae* in opposition to the petition for writ of certiorari is submitted on behalf of the Pharmaceutical Manufacturers Association (PMA).[1] PMA is a voluntary nonprofit association of 135 companies that are responsible for discovering, developing, manufacturing, obtaining Food and Drug Administration (FDA) approval of, and selling almost all of the pioneer prescription new drugs in this country.[2] One of the

[1] Letters from counsel for the parties consenting to the filing of this brief are being filed with the Clerk.

[2] In contrast, the members of the Generic Pharmaceutical Industry Association (GPIA), which is submitting a brief *amicus curiae* in support of the petition for writ of certiorari in this case, only rarely conduct research on, or otherwise develop, pioneer new drugs.

most important incentives in the development of these life-saving products is the United States patent system. Without patent protection, the enormous investment necessary for the development of a pioneer new drug would not be feasible.

This case strikes at the heart of patent protection. Petitioner Bolar Pharmaceutical Co., Inc. (Bolar), a generic drug company that does almost no developmental research of its own, asserts the right to encroach upon the patent of Roche Products, Inc. (Roche), in order to satisfy FDA regulatory requirements for marketing a generic drug. PMA believes that the decision of the United States Court of Appeals for the Federal Circuit, which petitioner Bolar asks this Court to review, is clearly correct in holding that the unlicensed use of a patented drug for development, testing, and other purposes in order to satisfy regulatory requirements is an illegal infringement, and the decision does not present any issue that warrants further review by this Court.

QUESTIONS PRESENTED

1. Is the unlicensed use of a patented drug, while the patent remains valid and unexpired, prohibited by the patent law where the user is conducting tests and experiments to adapt the patented invention to the user's business and to satisfy FDA regulatory requirements for marketing the product?

2. Can a generic drug company encroach upon the valid patent of a research-intensive pharmaceutical company and reduce the effective patent life by about two years by using the patented drug in order to satisfy FDA premarketing requirements prior to expiration of the patent term, where the effective patent life of the pioneer new drug is reduced by an average of seven to thirteen years while the research-oriented company conducted investigations to satisfy FDA premarketing requirements?

COUNTERSTATEMENT OF THE CASE

There are two categories of prescription new drugs marketed in the United States. The first category consists of the pioneer new drugs, developed by research-intensive pharmaceutical companies. It requires many years and millions of dollars to develop new pharmaceutical products and then to conduct the safety and effectiveness testing that is necessary to obtain FDA approval for marketing these drugs. The second category consists of generic copies of those pioneer new drugs. These copies require only a modest investment for marketing by generic drug companies like petitioner Bolar, which conduct no innovative new pharmaceutical research or development for these products.

Since enactment of the stringent regulatory requirements in the Drug Amendments of 1962,[3] the time required to develop and obtain FDA approval for a pioneer prescription new drug has increased from about 2 years to about 7-13 years. The cost of financing this process of innovation and regulatory approval for an average pioneer new drug has correspondingly escalated in constant dollars from about $6 million prior to 1962 to $44 million in 1972 and a great deal more today. The time needed to satisfy these requirements, moreover, inevitably is taken out of the innovator's patent life. Because a patent usually is filed and granted in the early years of drug innovation, every year required for testing and governmental approval reduces the effective patent life at the front end. A pioneer new drug approved for marketing by FDA today can be expected, as a result, to have an effective patent life of about half of the 17 years intended by Congress.

In contrast with this lengthy process that is required of the pioneer manufacturer, the generic manufacturer need spend only about 2 years to copy the pioneer drug, do the testing required, and obtain the expedited FDA approval that exists for these products.[4] Thus, generic manufacturers have an

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[3] 76 Stat. 780 (1962) (amending 21 U.S.C. § 355).

[4] Petition for writ of certiorari, p. 4.

enormous competitive advantage in copying the results of the research of pioneer manufacturers, with little investment and no risk.

In this case, Bolar used Roche's patented drug, while the patent remained valid and unexpired, to begin to perform the research required to formulate its own generic drug product.[5] Bolar also used the patented invention to begin to develop the data that must be submitted to FDA in order to obtain approval to market the generic drug product. Bolar asserts that it had the right to encroach upon Roche's patent, without authorization from Roche, for purposes of developing and testing its competitive drug product.

The Court of Appeals for the Federal Circuit held that this use by Bolar was an infringement of Roche's patent.[6] It is obvious that unlicensed use of a patented drug, in violation of a valid unexpired patent, directly injures the patent holder by depriving the patent holder of profits from the sale or licensing of the drug to other drug manufacturers, during the patent term, for whatever development and testing is necessary to satisfy regulatory requirements. The Court of Appeals decision prohibited Bolar from obtaining the benefits of such a sale or license arrangement without authorization from Roche.

Bolar also argued that it should be permitted to encroach upon the unexpired patent to develop its competitive product and to perform the tests required for FDA approval of the product so that it could compete with the patented product immediately upon expiration of the patent. According to Bolar, any other result would extend for 2 years after patent expiration the monopoly of patent holders in the pharmaceutical industry. The Court of Appeals rejected this argument. The Court recognized that Bolar was asking it to apply the patent laws to drugs differently than to other products. Because the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) requires Bolar to conduct testing and obtain FDA approval be-

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[5] Petition for writ of certiorari, p. 3.

[6] 733 F.2d 858 (Fed. Cir. 1984) (Appendix A to Petition for writ of certiorari).

fore it can market its generic drug product, Bolar wanted the Court to allow it to encroach upon a valid and unexpired patent for that two-year period. The Court of Appeals refused to allow this commercially significant encroachment in the guise of an expanded "experimental use" defense to liability for infringement.

REASONS FOR DENYING THE WRIT

The Federal Circuit's decision, which carefully reviewed and unanimously rejected petitioner's legal and factual claims, rests on settled patent law principles, is clearly correct, and does not present any issue that warrants further review by this Court.

I. The Federal Circuit's Decision Correctly Provides Strong Protection For Drug Patents, Consistent With The Constitution And Patent Law, At A Time When FDA Requirements For Approval Of New Drugs Have Substantially Reduced The Effective Patent Life Of These Products.

Section 505 of the Federal Food, Drug, and Cosmetic Act of 1938[7] required the manufacturer of a pioneer new drug to submit to FDA a new drug application (NDA) containing information relating to the safety of the drug. If FDA did not disapprove the drug within 60 days after receiving the NDA, marketing could begin.

Congress enacted the Drug Amendments of 1962[8] to strengthen Section 505[9] in light of the thalidomide disaster. Beginning in 1962, an NDA was required to contain data proving effectiveness as well as safety. FDA was also required affirmatively to approve the NDA rather than just to permit marketing by inaction.

The new drug requirements that existed between 1938 and 1962 were relatively innocuous and had little impact on the

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[7] 52 Stat. 1040 (1938).

[8] 76 Stat. 780 (1962).

[9] Section 505, as amended, is codified at 21 U.S.C. § 355.

development of pioneer prescription new drugs. The provisions of the Drug Amendments of 1962, however, have resulted in a substantial increase in the time required for development and approval of a pioneer new drug. Thus, FDA regulatory requirements have substantially reduced the effective patent life of pioneer new drug products.[10]

A. It Takes 7-13 Years During the Patent Term To Satisfy FDA Premarketing Requirements for Testing and Approval of Pioneer Prescription New Drugs.

As demonstrated in a 1980 Report by the House Subcommittee on Science, Research and Technology, FDA regulatory requirements impact upon the drug development process from the moment a new chemical entity is synthesized until final FDA approval of an NDA.[11] That process is divided into three major stages: preclinical research, clinical investigation, and NDA approval.

Preclinical Research. Before clinical investigation of a new chemical entity may begin, sufficient animal testing data must exist to justify use of the chemical in humans.[12] Innovators must also undertake substantial research on the chemical, pharmacologic, and toxicologic properties of the chemical during preclinical research. The FDA requirements for good laboratory practices (GLP) in conducting preclinical research for a new drug have substantially added to both the cost and the time for this type of research. Accordingly, it is not surpris-

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[10] The "effective patent life" of a drug is measured from the date of FDA approval of the NDA to the date of expiration of the patent.

[11] "The Food and Drug Administration's Process for Approving New Drugs," Report by the Subcommittee on Science, Research, and Technology, Committee on Science and Technology, House of Representatives, 96th Cong., 2d Sess. (1980) (hereafter "House Subcommittee Report"). *See also* Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973).

[12] Formal guidelines are issued by the FDA pursuant to 21 C.F.R. § 10.90(b). *See, e.g.*, 44 Fed. Reg. 20796 (April 6, 1979); 45 Fed. Reg. 41705 (June 20, 1980); 46 Fed. Reg. 24693 (May 1, 1981); 21 C.F.R. Part 58.

ing that the House Subcommittee Report found that preclinical research can take 1 to 4 years to complete.[13]

Clinical Investigation. Once adequate preclinical research is completed, innovators may submit the results of this research to FDA in order to obtain permission to begin clinical investigation of the investigational new drug (IND) in humans. Lengthy and detailed regulations and guidelines establish what FDA demands for evidence of safety and effectiveness of a pioneer new drug.[14] The House Subcommittee Report found that it takes about 4 to 6 years to conduct this IND research in accordance with FDA requirements in order to demonstrate that the drug is both safe and effective.

NDA Approval. After the FDA requirements for preclinical research and clinical investigation are completed, an NDA is submitted to FDA to obtain approval of the drug for marketing. Until that approval is obtained, the drug may not be commercialized. Although the statute requires FDA to act upon an NDA within 6 months, approval actually takes longer to obtain. The House Subcommittee Report found that the average NDA approval time was 14 months in 1963 and climbed to 35.2 months in 1979. During this substantial amount of time, the new drug cannot be marketed.

Summary. The House Subcommittee Report documents a period of 7-13 years to satisfy the requirements for preclinical research, clinical investigation, and NDA approval for a pioneer prescription new drug. This is in addition to the time needed to synthesize the new chemical entity before the drug development process itself can begin.

In contrast with this lengthy process that is required of the pioneer manufacturer, the generic manufacturer may spend only about 2 years to copy the pioneer drug, do the required testing, and obtain the expedited FDA approval that exists for

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[13] Note 11 *supra.*

[14] 21 C.F.R. Parts 50, 56, 312, 314.

these generic products.[15] Thus, generic manufacturers have an enormous competitive advantage in copying the results of the research of pioneer manufacturers, with little investment and no risk.

B. The Cost of Developing a Pioneer Prescription New Drug Has Escalated.

The cost of developing and obtaining approval of a pioneer prescription new drug has risen dramatically since 1962. It is estimated that about 10,000 candidate drugs are synthesized for every one that actually gets to market. For every ten drugs that reach the very expensive and time-consuming clinical investigation (IND) stage, only one is ultimately marketed.[16] The costs of chemical, animal, and clinical testing of pioneer new drugs have soared. As a result, the total amount of investment needed to produce a single approved pioneer new drug has increased exponentially.

The economic literature discloses several studies of the increase in the cost of developing a pioneer new drug in real

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[15] Petition for writ of certiorari, p. 4.

Unlike pioneer drug manufacturers, generic manufacturers do not conduct original research to discover new active drug ingredients. Rather, they take active drug ingredients developed by pioneer manufacturers and formulate products that are copies of the pioneer new drug product, except that the generic products may have different binders and excipients. Generic manufacturers do not perform the lengthy and expensive preclinical research and clinical investigations to show drug safety and effectiveness that are required of pioneer manufacturers. Instead, to obtain FDA approval of their products, generic manufacturers need only conduct short-term and thus inexpensive tests to show that their generic copies will perform in the same way as the pioneer drug product, that is, tests to show bioavailability (ability of the active ingredient to get into the bloodstream) and bioequivalence (equivalent rate and extent of absorption of the active ingredient). The results of these tests are submitted to FDA in an "abbreviated new drug application" (ANDA). This ANDA procedure permits expedited FDA approval of generic drug products. *See* 21 C.F.R. § 314.2 and Part 320.

[16] Wardell, "The History of Drug Discovery, Development and Regulation," in R.I. Chien, ed., *Issues in Pharmaceutical Economics* 10, 11 (1979).

dollars during the past 20 years. As demonstrated below, these studies show that the average cost of an approved pioneer new drug for 1962 was $6.5 million, and after 1962 it was $44.7 million, in 1980 dollars.[17]

Schwartzman found the R&D cost per pioneer new drug to be $1.3 million in 1960 and $24.3 million in 1973, excluding the cost of capital.[18] Adjusting these figures to 1980 dollars ($3.7 million and $48.6 million), this reflects a 13-fold increase in the real cost of a pioneer new drug in this 10-year period.

Sarett found the cost per approved drug (not per pioneer new drug) in one pharmaceutical firm to be $1.2 million in 1962, $3.0 million in 1967, and $11.5 million in 1972, excluding the cost of unsuccessful projects, capital, and discovery research.[19] Adjusting the 1962 and 1972 figures to 1980 dollars ($3.4 million and $25.9 million), they reveal a 7.6-fold increase in this 10-year period.

Mansfield[20] and Schnee[21] jointly studied some 75 drug research projects undertaken in one pharmaceutical firm during the period 1950 to 1957. For the period prior to 1962, R&D cost per marketed pioneer new drug was $1.1 million, or $3.1 million in 1980 dollars, excluding the cost of capital and discovery research.

Clymer found that the R&D cost for a marketed pioneer new drug in one pharmaceutical company in 1971 was $12 million.[22]

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[17] *See* Appendix A, summarizing the results of the studies.

[18] Schwartzman, *Innovation in the Pharmaceutical Industry* 65-70 (1976).

[19] Sarett, "Impact of Regulations on Industrial R&D: FDA Regulations and Their Influence on the Future of R&D," *Research Management* 18 (March 1974).

[20] Mansfield, Panel Discussion, in J.D. Cooper, ed., *Economics of Drug Innovation* 149 (1969).

[21] Schnee, "Development Costs, Determinants and Overruns," *Journal of Business* 347 (July 1972).

[22] Clymer, "The Economics of Drug Innovation," in Parnowski & Darrach, ed., *The Development and Control of New Drug Products* 109 (1972).

Clymer also found that the R&D discovery cost amounts "to at least as much as the development costs" for a pioneer new drug, thus making the total costs approximately $24 million in 1971 or $56.5 million in 1980 dollars, excluding the cost of capital.[23]

Hansen, using an accounting approach, directly studied R&D expenditures based on a sample of new chemical entity drugs from several drug companies.[24] He found the average cost between 1963 and 1975 to be $54 million. Expressed in 1980 dollars, this amounts to $70 million including the cost of capital and $47.6 million excluding the cost of capital.

Baily developed a model of new product development and applied it to the pharmaceutical industry on the basis of aggregate industry figures.[25] He projected $6 million per pioneer new drug before 1962, or $16 million in 1980 dollars.

The table in Appendix A summarizes these 6 studies. These figures do not, of course, show the increase in real R&D cost per approved pioneer drug for the past 10 years. They show only the increase during the 10-year period from about 1962 to 1972. If figures were available during the past 10 years, they would show a further increase in the real R&D cost per approved pioneer new drug. Nonetheless, the available studies show that the average cost of an approved pioneer new drug before 1962 was $6.5 million, and after 1962 it was $44.7 million, in 1980 dollars. This represents a real 6.9-fold increase even without including the cost of capital.

Thus, for any given level of research and development investment by the pharmaceutical industry today, the country realizes fewer pioneer new drugs than it once did. Because of

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[23] Clymer, "The Changing Costs and Risks of Pharmaceutical Innovation," in J.D. Cooper, ed., *Economics of Drug Innovation* 123 (1969).

[24] Hansen, "The Pharmaceutical Development Process: Estimates of Development Costs and Times and the Effects of Proposed Regulatory Changes," in R.I. Chien, *Issues in Pharmaceutical Economics* 151 (1979).

[25] Baily, *Research and Development Costs and Returns: The U.S. Pharmaceutical Industry*, 80 J. Pol. Economy 78 (January/ February 1972).

this decrease in real investment by the industry, it is not surprising that a 1983 study by the National Academy of Engineering documented a substantial decline in pharmaceutical innovation in the United States:[26]

> "Data compiled by this study indicate a clear relative deterioration in the foundation of pharmaceutical competitive position — the research efforts necessary for discovery and introduction of new patented drugs."

Strong patent protection is an essential element in reversing this deterioration.

C. The Effective Patent Life of a Pioneer Prescription New Drug Has Been Cut in Half as a Result of FDA Regulatory Requirements.

Although Congress has not changed the 17-year patent term for pharmaceutical products, the increase in FDA research, testing, and approval requirements just described has reduced the effective patent life of a pioneer prescription new drug by half.

When a research-intensive pharmaceutical firm discovers a new chemical compound with promising biological activity, the first thing it does is to file for a patent, even before making the investment to develop the entity into a marketable medicine. Once that patent is issued, its 17-year term immediately begins to run. But at the time the patent is issued, the innovating firm may be far from sure it will ever develop a marketable drug. For that assurance, the law requires FDA approval of an NDA which, as documented above, takes 7-13 years to obtain.

For pharmaceutical products, therefore, the 17-year patent term has become a legislative figment. In reality, a drug patent has a much shorter effective life. As a result, incentives to invest in pharmaceutical research and development have been substantially reduced.

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[26] National Academy of Engineering, *The Competitive Status of the U.S. Pharmaceutical Industry* 1 (1983).

The erosion of effective patent life[27] for pharmaceutical products began about 20 years ago. It coincides with the erosion in pharmaceutical innovation, as measured by the yearly FDA approval of pioneer new drugs.

A number of studies have been conducted regarding the precise reduction that has occurred in the effective patent life for pioneer prescription new drugs during the past twenty years. All studies show the same trend. Both individually and in combination, they confirm a substantial decrease in effective drug patent terms. The effective patent life of the pioneer new drugs approved by FDA in 1980 and 1981 was less than half the 17 years provided by Congress under the patent law.

Pracon, Inc., an independent consulting firm, found that the average effective patent life of pioneer new drugs approved by FDA during the period 1950 to 1977 was reduced from 12.9 years to 8.8 years between 1966 and 1977.[28]

Schwartzman studied the pioneer new drugs approved by FDA during 1966 to 1973.[29] He calculated the arithmetic mean of their effective patent life during this time to be 13.1 years. Moreover, he found a progressive reduction in the average effective patent life during that period, from 13.9 years between 1966 and 1973 to 12.4 years between 1970 and 1973.

Statman studied a sample of 126 pioneer new drugs approved by FDA between 1949 and 1975.[30] He found "a continuous decline in the effective life of drug patents" and developed an equation to estimate the effective life of drug patents for 1960 to 1978.

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[27] Note 10 *supra*.

[28] Pracon, Inc., *The Effective Patent Life of Pharmaceutical Products: Trends and Implications* (1978).

[29] Schwartzman, *Innovation in the Pharmaceutical Industry* 167-173 (1976).

[30] Statman, "The Effect of Patent Expiration on the Market Position of Drugs," in R.B. Helms, ed., *Drugs and Health: Economic Issues and Policy Objectives* 140 (1980) and in *Managerial and Decision Economics* 61 (June 1981).

Eisman and Wardell studied the effective life of pioneer new drug patents during 1966 to 1979.[31] They found the average effective patent life declined from 13.6 years in 1966 to 9.5 years in 1979.

The Pharmaceutical Manufacturers Association obtained additional data for the year 1980.[32] They show that, for pioneer new drugs approved by FDA in 1980, the average effective patent life decreased still further, to 7.4 years.

Wardell recently obtained the patent data for pioneer new drugs approved by FDA in 1981. They show an even lower average effective patent life of 6.8 years.[33]

In order graphically to illustrate the results of these studies, they are plotted on the chart shown in Appendix B. The congruence of these studies is striking.

II. The Unlicensed Use Of Patented Drugs For The Purpose Of Developing Generic Drug Products And Conducting The Tests Required For FDA Approval Directly Injures The Patent Holder.

The patent law specifically defines as an illegal infringer any person who "makes, uses, or sells" a patented product during the term of the patent. 35 U.S.C. § 271(a). There are sound reasons why the law thus prohibits *any* "use" of a patented product while the patent remains valid and unexpired, as illustrated by the situation involved in this case.

Use of a patented drug, in violation of a valid unexpired patent, directly injures the patent holder by depriving the patent holder of profits from the sale or licensing of the drug to

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[31] Eisman & Wardell, "The Decline in Effective Patent Life of New Drugs," *Research Management* 18 (January 1981).

[32] "Patent Term Extension and Pharmaceutical Innovation," Hearing before the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, House of Representatives, 97th Cong., 2d Sess. 159-160 (1982).

[33] *Id.* at 110-112.

other drug manufacturers, during the patent term, for whatever testing is necessary to satisfy regulatory requirements.

Research-intensive pharmaceutical companies may sell an active ingredient to another drug manufacturer, or may license another drug manufacturer to make or use an active ingredient, during the term of a patent. Such contractual arrangements permit the other manufacturers to conduct the testing necessary to satisfy FDA regulatory requirements before the patent expires. Such sales or licenses generate profits for the patent holder.

Bolar seeks to obtain the benefits of such an arrangement without any license from Roche. In effect, Bolar is appropriating unto itself a compulsory license without compensation. The patent law nowhere provides for such an extraordinary result. Congress has on several occasions explicitly declined to enact legislation that would require compulsory patent licensing, either for all patents generally or for new drug patents in particular, even with compensation.[34] For this reason alone, Bolar's arguments were properly rejected by the Court of Appeals.

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[34] *E.g.*, S. 1552, 87th Cong., 1st Sess. (1961) (Kefauver); H.R. 6245, 87th Cong., 1st Sess. (1961) (Celler); S. 1297, 88th Cong., 1st Sess. (1963) (Kefauver); S. 2287, 93d Cong., 1st Sess. (1973) (Hart); H.R. 915, 97th Cong., 1st Sess. (1981) (Rosenthal). *See* "Drug Industry Antitrust Act," Hearings before the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary, United States Senate, 87th Cong., 1st Sess., Parts 1-5 (1961); "Administered Prices — Drugs," S. Rep. No. 448, 87th Cong., 1st Sess. (1961); "Drug Industry Antitrust Act," Hearings before the Antitrust Subcommittee of the Committee on the Judiciary, House of Representatives, 87th Cong., 2d Sess. (1962). Congress has adopted compulsory licensing only for particular areas such as air pollution technology, 42 U.S.C. § 7404, and atomic energy, 42 U.S.C. § 2183.

III. The Federal Circuit Properly Declined To Create For Generic Drug Companies A New Exception To The Use Prohibition Which Would Further Erode Patent Protection For Pioneer New Drugs And Would Thus Be Contrary To The Patent Law And Harm Public Health In The United States.

The patent law clearly provides that the unlicensed use of a patented product during the patent term is an infringement. Bolar asked the Court of Appeals to create an exception to this use prohibition that would allow generic drug companies to use patented pioneer new drugs, without license from the patent holder, to conduct all of the necessary formulation and tests to obtain FDA approval of the generic drug product before expiration of the patent term. This would allow generic drug companies to offer their products in competition with the patented product immediately upon expiration of the patent, rather than requiring them to comply with the requirements of the Federal Food, Drug, and Cosmetic Act after expiration of the patent. In essence, Bolar requested permission from the Federal Circuit to violate the patent law in order to avoid marketing delays imposed by the federal drug law and FDA regulatory requirements. The Court of Appeals properly refused to create this exception for generic drug companies.

This Court has repeatedly recognized and reinforced "the policy of stimulating invention that underlies the entire patent system."[35] Without the stimulus of the temporary period of exclusivity provided under the patent law, there would be far less incentive for pharmaceutical companies to invest their funds in risky pharmaceutical R&D ventures than in other competing investment opportunities.[36]

The data discussed above document the substantial decline since 1962 in the effective patent life of pharmaceutical products, the increase in the cost of developing pioneer new drugs,

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[35] Dawson Chemical Co. v. Rohm & Haas Co., 448 U.S. 176, 221 (1979).

[36] This was recognized by the court in Eli Lilly and Co. v. Premo Pharmaceutical Laboratories, Inc., 630 F.2d 120, 137 (3d Cir.), *cert. denied*, 449 U.S. 1014 (1980).

and the reduction in pharmaceutical innovation. The importance of patent protection obviously increases with the size of the investment needed to achieve innovation in any field. If innovation can be purchased cheaply patent protection is relatively unimportant. As the investment cost escalates, however, patent protection becomes far more important. In the pharmaceutical industry, where the cost of a pioneer new drug has escalated so dramatically, the assurance of strong patent protection has become increasingly crucial to the future of the industry. This fact has been explicitly recognized in recent reports by the National Academy of Engineering[37] and by the Office of Technology Assessment,[38] in the Patent Amendments of 1980,[39] and in a 1968 General Accounting Office report on pharmaceutical research.[40] Without an adequate patent system, innovation in the pharmaceutical industry would wither and the public health would correspondingly suffer.

Pioneer new drugs represent our major hope as a society for reducing the burden of morbidity and mortality in this country. The infectious diseases that took such a heavy human toll at the turn of the century now cause less than 2 percent of the deaths they caused then.[41] Diseases dreaded as recently as 30 years ago now largely are under control. New pharmaceutical products have played a key role in the declining rates of death and disease for a wide variety of serious disease categories.[42] New

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[37] National Academy of Engineering, *The Competitive Status of the U.S. Pharmaceutical Industry* 79-80 (1983).

[38] Office of Technology Assessment, *Patent Term Extension and the Pharmaceutical Industry* 28 (1981).

[39] 94 Stat. 3015, 3019 (1980).

[40] General Accounting Office, *Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry*, Report No. B-164031(2), 18-19 (1968).

[41] Fries, "Aging, Natural Death, and the Comprehension of Morbidity," 303 *New Eng. J. Med.* 130, 132 (July 17, 1980).

[42] These disease categories include measles, mumps, rheumatic fever, rubella, tuberculosis, whooping cough, and meningitis. *See* National Center for Health Statistics, *Monthly Vital Statistics Reports — Annual Summary*

medicines to achieve the same dramatic results against our current leading causes of death — heart disease and cancer — are now major targets for the pharmaceutical industry. Pharmaceutical innovation is also a primary means through which the skyrocketing costs of health care can be brought under control and perhaps eventually even reduced.

Extraordinary investments are needed to assure that the insights provided by new scientific information are translated into pioneer new drugs in the future. Whether those investments will occur, however, depends in substantial part upon the incentives provided by a strong patent system. By preserving the integrity of the patent term of pioneer new drugs against attempted encroachment by generic drug companies, the Court of Appeals has preserved the current and necessary stimulus to innovation in the pharmaceutical industry.

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of Births, Deaths, Marriage and Divorce: United States, 1980, Vol. 29, No. 13, p. 20 (1981); National Center for Health Statistics, *Vital Statistics of the United States, 1960*, Vol. 2, Pt. A, pp. 5-102 (1961); U.S. Department of Health and Human Services, *Morbidity and Mortality Weekly Report — Annual Summary, 1981*, Vol. 29, No. 56, pp. 12 & 14 (September 1981); U.S. Department of Health, Education and Welfare, *Morbidity and Mortality Weekly Report — Annual Supplement, 1961*, Vol. 29, No. 54, p. 4 (September 1961).

CONCLUSION

For the reasons set forth above, the petition for a writ of certiorari should be denied.

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APPENDICES

APPENDIX A

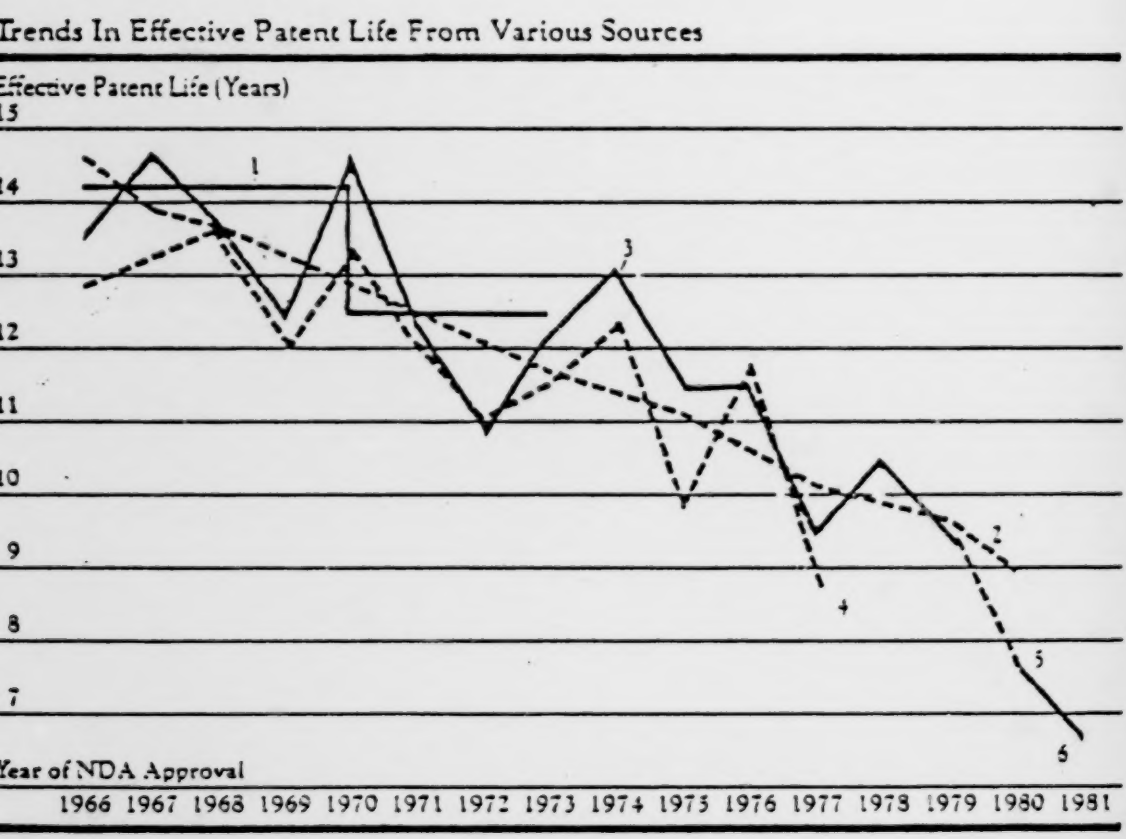
Real Research and Development Costs per Pioneer Prescription New Drug: 1962-1972

	Pre-1962	Post-1962
Schwartzman	3.7	48.6
Sarett	3.4	25.9
Mansfield/Schnee	3.1	—
Clymer	—	56.5
Hansen	—	47.6
Baily	16.0	—
Average	6.5	44.7

NOTE: All figures adjusted to 1980 dollars.

APPENDIX B

Trends In Average Effective Patent Life Of Pioneer Prescription New Drugs, 1966-1981



1. Schwartzman 2. Seaman 3. Eisman & Wardell 4. Prascon 5. PMA 6. Wardell.